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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/848,820	05/19/2004	Timothy A. McKinsey	MYOG:044US/10405748	4787

32425 7590 07/06/2009

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EXAMINER	
SCHUBERG, LAURA J	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
07/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/848,820	MCKINSEY ET AL.	
	Examiner	Art Unit	
	Laura Schuberg	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-11 and 100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-11 and 100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to papers filed 03/13/2009. Claims 1 and 100 have been amended. Claim 6 has been canceled. Currently claims 1-4, 7-11 and 100 are pending.

Response to Amendment

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 7-11 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dempsey (US 6,228,843) in light of Wang (Trends Pharmacol Sci, June 2006) and Matthews et al (J Biol Chem, August 1997) and in view of Metra et al (Heart failure Reviews 1999).

Amended claim 1 is drawn to a method of treating pathologic cardiac hypertrophy or heart failure in a human patient comprising: (a) identifying a human patient having cardiac hypertrophy or heart failure; (b) administering an inhibitor of PKD; and (c) administering a beta blocker.

Dependent claims include wherein the inhibitor of PKD is selected from a group, the type of administration, the timing of the beta blocker administration, wherein treating comprises improving one or more symptoms of cardiac hypertrophy or heart failure.

Dempsey teaches a treatment method of treating cardiac hypertrophy and cardiac failure (column 14 lines 28-33). Treatment can comprise administering several drugs to inactivate protein kinase C. Specifically the drugs taught include bryostatin and Go6976 (see Fig. 4; see col. 3 line 62 to line 67, as examples). Dempsey teaches that his method functions by first activating PKC which then causes its degradation (see col. 11 lines 35-40, for example).

Wang teaches that PKD is phosphorylated by PKC.

Matthews et al teach that bryostatin activates PKD through PKC (see Abstract, for example); therefore it is inherent that administration of bryostatin causes degradation of PKC and inhibition of PKD signaling as taught by Dempsey. These drugs are effective in primates including humans, reading on the limitation that the patient is human (see col. 4, lines 1-6, for example). The drugs administered in combination with bryostatin include staurosporine, ACE-I (ACE inhibitors), and calcium channel blockers (Ca^{2+}-blocker) for example (see col. 12, lines 32-45, for example). They teach that the drugs can be administered in an oral or intravenous manner (see col. 6 lines 39-53, for example). Preferably the patient is treated by this method to an extent that the patient no longer suffers from the condition or wherein the discomfort and/or altered functions and detrimental conditions associated with the disease are decreased (column 9 lines 1-16). This is deemed to meet the limitation wherein the improved symptom is an increased quality of life.

Dempsey does not specifically teach administering the drug in combination with a beta blocker.

Metra et al teach that beta blockers when administered in combination with other drugs, such as ACE inhibitors, to patients with heart failure have been shown to be effective tools to improve cardiac function and the clinical course of the disease (page 65 column 1). Metra et al teach that the role of agents with proven efficacy on the survival and clinical course of the disease, like ACE inhibitors and beta blockers, as first line therapies for heart failure should be reinforced (page 68 column 2).

Therefore one of ordinary skill in the art would have been motivated to add the beta blockers and ACE inhibitors to the drug composition of Dempsey because Metra et al teach that these drugs have been shown to improve cardiac function and the clinical course of the disease and Dempsey suggests including drugs like ACE inhibitors as well. One of ordinary skill in the art would have had a reasonable expectation of success because Dempsey also suggests combining drugs known to be beneficial in the treatment of heart disease.

Therefore the combined teachings of Dempsey, Wang, Matthews et al and Metra et al render obvious Applicant's invention as claimed.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 7-11 and 100 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura Schuberg

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657